

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and	)	
HOFFMANN-LA ROCHE INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 18-95 (GMS)
	)	
CELLTRION, INC., CELLTRION	)	
HEALTHCARE, CO. LTD., TEVA	)	
PHARMACEUTICALS USA, INC., and	)	
TEVA PHARMACEUTICALS	)	
INTERNATIONAL GMBH,	)	
	)	
Defendants.	)	

**PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR  
MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS**

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## **I. INTRODUCTION**

Eight months ago, Celltrion abandoned the patent dance and filed suit in its favored forum, California. But that strategic decision came with a price: by failing to complete the patent dance as required by the BPCIA, Celltrion forfeited the right to bring declaratory-judgment claims, including the declaratory-judgment counterclaims that it has asserted here.

To avoid the consequence of its failed strategy, Celltrion makes arguments that are contrary to the BPCIA's carefully calibrated scheme to resolve patent disputes. First, Celltrion argues that the BPCIA's declaratory-judgment bar does not apply to counterclaims, but this runs counter to the plain language of the statute and would lead to outcomes that are contrary to its goals. Second, Celltrion seeks to avoid the consequences of its abandonment of the patent dance by arguing that the BPCIA allows a biosimilar applicant to unilaterally and indefinitely pause the patent dance. But this argument also finds no support in the BPCIA's text, and it would result in a system that is the opposite of the orderly and expeditious process that Congress intended.

If Celltrion had complied with the patent dance and indicated a desire to litigate all of the patents asserted by Genentech in this case, Genentech would have sued it on those patents in March, and Celltrion could have brought its counterclaims. But Celltrion instead launched a several-month campaign to push the limits of the BPCIA for its own strategic benefit. The BPCIA's penalty for these actions may create uncertainty for Celltrion, but it is uncertainty that Celltrion brought on itself. Celltrion's attempts to rewrite the BPCIA to avoid the consequences of its calculated decision not to engage in the patent dance should therefore be rejected, and its counterclaims should be dismissed in their entirety.

## **II. ARGUMENT**

### **A. Section 262(l)(9)(B)'s declaratory-judgment bar applies to counterclaims.**

Celltrion devotes the bulk of its brief to a novel statutory argument: that bringing a

counterclaim is different from “bring[ing] an action,” as that phrase is used in the BPCIA’s declaratory-judgment bar, 42 U.S.C. § 262(l)(9)(B). Celltrion’s reading of the statute is contrary to both its plain language and its policy goals. To preserve the BPCIA’s “carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement,” *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017), Celltrion’s unduly narrow reading of § 262(l)(9)(B) should be rejected.

Begin with the statute’s text. Section 262(l)(9)(B) provides that:

***If a subsection (k) applicant fails to complete an action*** required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), ***the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28 . . . .***

42 U.S.C. § 262(l)(9)(B) (emphasis added). The structure of the statute is straightforward: if a biosimilar applicant, like Celltrion, fails to complete certain actions, then the applicant is barred from “bring[ing] an action” for a declaratory judgment.

Celltrion does not dispute that a counterclaim is an “action” as that term is generally understood. Indeed, it cannot—courts routinely conclude that a counterclaim is an “action” under a diverse array of federal and state statutes. *See, e.g., Fed. Deposit Ins. Corp. v. S & I 85-1, Ltd.*, 22 F.3d 1070, 1074 (11th Cir. 1994) (concluding that “counterclaims filed by the Defendants constituted an ‘action, suit, or proceeding’ within the meaning of” 12 U.S.C. § 1819(b)(2)(B)).<sup>1</sup> Even the main case that Celltrion relies on, *Jonathan H. v. The Souderton*

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<sup>1</sup> There are many other cases to this effect interpreting many similar statutes. *See, e.g., In re Merrick*, 175 B.R. 333, 337 (B.A.P. 9th Cir. 1994) (concluding that “a counterclaim is ‘an action or proceeding against the debtor’” under 11 U.S.C. § 362(a)(1), which provides for an automatic stay in bankruptcy); *First Specialty Ins. Corp. v. Cont’l Cas. Co.*, No. 01 C 9175, 2002 WL 31386521, at \*4 (N.D. Ill. Oct. 21, 2002) (concluding that a “counterclaim constitutes an ‘action or proceeding’ that was ‘instituted against’” the plaintiff under 215 ILCS § 5/123); *New Mexico ex rel. Energy & Minerals Dep’t, Min. & Mineral Div. v. U.S. Dep’t of Interior*, No. CIV.A. 84-

*Area School District*, 562 F.3d 527 (3d Cir. 2009), explains that “[t]he word ‘action,’ without more, is arguably broad enough to encompass any type of judicial proceeding, including counterclaims.” *Id.* at 529 (citing definitions of “action” that are broad enough to include counterclaims from the Seventh Circuit, *Black’s Law Dictionary*, and the UCC). And other sections of the Patent Act confirm that a counterclaim, by default, is an “action.” Section 315, for example, provides that “[a]n inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest **filed a civil action** challenging the validity of a claim of the patent.” 35 U.S.C. § 315(a)(1) (emphasis added). But it goes on to say that “[a] counterclaim . . . does not constitute a civil action . . . for purposes of this subsection.” *Id.* § 315(a)(3). If a counterclaim were not generally understood to be an “action,” there would be no need for this carve-out.

Finding no help in prior interpretations of “action,” Celltrion focuses its argument on the word “bring,” suggesting that this word somehow limits an “action” to the filing of a complaint. But there is nothing inherent in the word “bring” that excludes counterclaims. Courts routinely refer to parties “bringing a counterclaim.” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 413 (2012) (“An ANDA applicant sued for patent infringement may **bring a counterclaim** on the ground that the patent does not claim an approved method of using the drug.”) (cleaned up, emphasis added).<sup>2</sup> And leading treatises and law dictionaries, including

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3572, 1985 WL 6081, at \*3 (D.D.C. Nov. 6, 1985), *vacated on other grounds*, 820 F.2d 441, 447 (D.C. Cir. 1987) (concluding that a “counterclaim is an action within the scope of the citizen suit provision of SMCRA,” 30 U.S.C. § 1270(c)(1), which provided that “[a]ny action respecting a violation of this chapter . . . may be brought only in the judicial district in which the surface coal mining operation complained of is located”).

<sup>2</sup> This is one of many examples. *See, e.g., Prudential Ins. Co. of Am. v. Hovis*, 553 F.3d 258, 264 (3d Cir. 2009) (“[W]here a claimant **brings an independent counterclaim** against the stakeholder, the stakeholder is kept in the litigation to defend against the counterclaim . . .”) (emphasis added); *E.I. DuPont De Nemours & Co. v. Unifrax I LLC*, C.A. No. 14-1250-RGA,



those Celltrion cites, do as well.<sup>3</sup> Because a counterclaim is generally understood to be an action, the phrase “bring an action” in § 262(l)(9)(b) includes bringing a counterclaim.

To be sure, “[o]ne ‘brings’ an action by commencing suit.” D.I. 45 (“Opp.”) at 10 (quoting *U.S. ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 362 (7th Cir. 2010)).

But that is not the **only** way to “bring an action.” A case Celltrion cites goes on to explain:

Many statutes are of the form “do not bring an action until ...”, where the condition is exhausting administrative remedies, negotiating, or waiting a specified time. Statutes of this form are understood to forbid the commencement of a suit; an action (***or a given claim within a larger action***) “brought” while the condition precedent is unsatisfied must be dismissed . . . .

*Chovanec*, 606 F.3d at 362 (emphasis added). That is precisely the form of the BPCIA’s declaratory-judgment bar, which forbids a biosimilar applicant from bringing a declaratory-judgment action unless and until it has satisfied the patent dance’s requirements. There is simply no reason to conclude, based on the plain language of § 262(l)(9)(B), that a counterclaim—which is a “claim within a larger action”—is exempt from this restriction.

Celltrion cites essentially a single instance of “bring an action” being construed to exclude a counterclaim: the Third Circuit’s *Jonathan H.* decision, which involved judicial review of an administrative decision issued under the Individuals with Disabilities Education Improvement Act of 2004, 20 U.S.C. § 1415 (the “IDEA”). 562 F.3d at 528; *see also Ruben A. v. El Paso Indep. Sch. Dist.*, 414 F. App’x 704 (5th Cir. 2011) (adopting *Jonathan H.*’s holding,

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2015 WL 4641615, at \*1 (D. Del. Aug. 5, 2015) (“[I]f all that were necessary to **bring state law counterclaims** was an allegation of invalidity and/or non-infringement, with an allegation of ‘bad faith,’ one would expect to see these sorts of counterclaims in most patent litigation.”) (emphasis added). A Westlaw search for “bring” within three words before “counterclaim” returns over 500 federal cases in the last three years.

<sup>3</sup> *See, e.g., Black’s Law Dictionary* 305 (8th ed. 2004) (noting, in the definition of “compulsory-counterclaim rule,” that “[m]ost courts hold that if a party does not timely **bring a compulsory counterclaim**, the party is estopped from asserting the claim”) (emphasis added); 6 Wright & Miller, *Federal Practice & Procedure* §§ 1403, 1404 (3d ed. Apr. 2018 update).

without further analysis, in another IDEA case). But *Jonathan H.* interpreted “bring an action” in a different context from the BPCIA, and its logic should not be extended to this case.<sup>4</sup>

The IDEA allows a student to seek certain accommodations from a public school before an administrative hearing officer. *Jonathan H.*, 562 F.3d at 528. If the student or the school is dissatisfied with the hearing officer’s decision, it may “bring a civil action” seeking judicial review. 20 U.S.C. § 1415(i)(2)(A). “The party bringing the action shall have 90 days from the date of the decision of the hearing officer to bring such an action.” *Id.* § 1415(i)(2)(B).

In *Jonathan H.*, neither the student nor the school was satisfied with the hearing officer’s decision. *See* 562 F.3d at 528. The student filed a civil action challenging it on the last day of the limitations period, and the school filed counterclaims challenging the decision with its answer several weeks later. *Id.* The case was formally a civil action presenting cross-motions for summary judgment, but it was functionally the same as a cross-appeal.

The district court deemed the school’s counterclaims untimely because they were brought after the 90-day limitations period expired, *id.*, but the Third Circuit reversed. The Third Circuit concluded that “a defendant does not ‘bring an action’ by asserting a counterclaim; only a plaintiff may ‘bring an action’ *for purposes of the IDEA.*” *Id.* at 530 (emphasis added). Policy concerns were pervasive in the Third Circuit’s decision. The court explained, for example, that

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<sup>4</sup> Celltrion also cites two cases suggesting that a party “bring[s] an action” by initiating it. These cases, however, are about the *timing* of when an action is deemed brought, not about whether counterclaims constitute “bring[ing] an action,” which is the issue in this case. In *Chandler v. D.C. Department of Corrections*, 145 F.3d 1355, 1358 (D.C. Cir. 1998), Congress enacted a cap on the number of times a prisoner could “bring a civil action or appeal a judgment” *in forma pauperis* while the appeal was pending. The appeal would have been barred if the cap applied, but the court held that it did not because “bring a civil action or appeal a judgment” referred to the act of initiating a suit or an appeal, not prosecuting one that had already been initiated. *Id.* at 1358. Likewise, *Beeler-Lopez v. Dodeka, LLC*, 711 F. Supp. 2d 679, 681 (E.D. Tex. 2010), held that a debt collector’s new counsel was not liable under the Fair Debt Collection Practices Act for taking over an improperly venued action because the new counsel did not “bring” (i.e., initiate) the action. Neither decision considered counterclaims.

its interpretation resulted in the “fairer rule,” since it prevented a scenario in which a party could lose its right to effectively cross-appeal a mixed judgment because of its adversary’s gamesmanship. *Id.* It also noted that its interpretation prevented “unnecessary litigation” by eliminating the need for all parties to “file ‘protective complaints’ to preserve issues adjudicated against them, even when they otherwise would countenance the administrative judgment.” *Id.*

Genentech is unaware of any court extending *Jonathan H.*’s reasoning beyond the IDEA, and Celltrion cites none. And the policy concerns underlying *Jonathan H.* simply are not present in the context of the BPCIA. A biosimilar applicant like Celltrion only becomes subject to the BPCIA’s declaratory-judgment bar if it “fails to complete an action required of [it] under” the patent dance. 42 U.S.C. § 262(l)(9)(B). There is no scenario in which a reference product sponsor’s gamesmanship can cause the biosimilar applicant to lose its right to pursue declaratory-judgment claims—only the biosimilar applicant’s actions, like Celltrion’s decision to intentionally forgo the patent dance and sue Genentech in California, can do that.

Celltrion’s policy argument for excluding counterclaims from § 262(l)(9)(B) fares no better than its textual argument. Celltrion contends that any interpretation of § 262(l)(9)(B) that denies it “certainty . . . for the commercial launch of biosimilar products” is contrary to Congress’s intent. Opp. at 12. But the BPCIA only grants a biosimilar applicant “certainty” when it complies with the patent dance, which Celltrion did not do here. *Cf. Sandoz*, 137 S. Ct. at 1672 (noting “various consequences for failing” to comply with the patent dance). And Celltrion also presents a one-sided picture of the BPCIA’s goals, which also include resolving disputes “expeditiously” and “providing certainty to . . . the reference product manufacturer[] and the public at large.” *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016) (omitted parts of legislative history sentence that Celltrion quotes at Opp. 12). As Genentech’s

opening brief explains, there must be meaningful penalties to ensure that a biosimilar applicant complies with the patent dance, D.I. 41 at 12-13, which is the “carefully calibrated scheme” that Congress created to balance the statute’s competing goals, *Sandoz*, 137 S. Ct. at 1670.<sup>5</sup> There is nothing inequitable about penalizing parties like Celltrion—which abandoned the patent dance and filed a statutorily-barred complaint—for upsetting this balance for their own strategic ends.

And if “certainty” is what Celltrion wants, its proposed interpretation of the BPCIA is not the way to get it. To ensure that a biosimilar applicant is on notice of the patents its product might infringe, the BPCIA requires the reference product sponsor (i.e., Genentech) to provide the applicant with a list of all such patents (i.e., a 3A List). *See* 42 U.S.C. § 262(l)(3)(A). If the sponsor fails to include a patent on its 3A List (or an appropriate supplement, per § 262(l)(7)), it cannot sue the applicant for infringing the patent. The BPCIA specifically provides that:

The owner of a patent that should have been included in the [3A] list [or an appropriate supplement] for a biological product, but was not timely included in such list, ***may not bring an action*** under this section for infringement of the patent with respect to the biological product.

35 U.S.C. § 271(e)(6)(C) (emphasis added).<sup>6</sup>

It is a “normal rule of statutory interpretation that identical words used in different parts of the same statute are generally presumed to have the same meaning.” *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005). If Celltrion is right that “bring an action” in § 262(l)(9)(B) excludes

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<sup>5</sup> Celltrion suggests, without citing any authority, that § 262(l)(9)(B) is only meant to “guarantee[] the reference product sponsor’s right to initiate the first phase of litigation in its chosen forum” and not to create penalties for non-compliance with the patent dance. Opp. at 12. That is plainly wrong. At least one of the failures to act that triggers § 262(l)(9)(B) necessarily occurs after the first-phase complaint is filed. *See* 42 U.S.C. § 262(l)(6)(C)(i) (requiring the biosimilar applicant to provide notice of the first-phase complaint to the Secretary of Health and Human Services). Interpreting § 262(l)(9)(B) as narrowly as Celltrion suggests would render that requirement meaningless.

<sup>6</sup> The BPCIA amended both Title 42 and Title 35 of the U.S. Code. *See* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).

counterclaims, then “bring an action” in § 271(e)(6)(C) does too. This would allow Genentech to assert any patent in its portfolio against Celltrion as a counterclaim in any case in which Celltrion is a plaintiff (e.g., in its California case, if it is revived on appeal, or in a second-phase BPCIA case). This outcome—which would render the narrowing functions of the patent dance meaningless—would create far more uncertainty for Celltrion than dismissing its counterclaims would. Celltrion will almost certainly disagree with this reading of § 271(e)(6)(C), but there is no way to reconcile that disagreement with Celltrion’s interpretation of § 262(l)(9)(B).

The plain meaning of “bring an action” encompasses bringing counterclaims. Nothing in the BPICA supports deviating from that plain meaning, and the policy underlying the statute provides ample reason for refusing to do so. Celltrion’s strained statutory interpretation argument should accordingly be rejected.

**B. Celltrion’s counterclaims are barred by § 262(l)(9)(B).**

Celltrion next tries to salvage its counterclaims by arguing that it discharged its statutory duties either before it filed its California complaint or when it served its untimely “5A Number” in June. Neither argument bears scrutiny. Because Celltrion failed to complete its obligations under § 262(l)(9)(B), its counterclaims should be dismissed.

*First*, Celltrion’s attempt to rehash whether it had complied with § 262(l)(5) when it filed its California complaint is both procedurally improper and without merit. Celltrion concedes, as it must, that the California court dismissed its complaint because the court “conclud[ed] that Celltrion failed to complete the paragraph (5)(A) list exchange by the time it filed suit.” Opp. at 13. Final judgment has entered in that case, D.I. 42, Ex. 6, so Celltrion is collaterally estopped from relitigating the issue here.<sup>7</sup> And even if the Court were to consider these arguments, the

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<sup>7</sup> See, e.g., *United Access Techs., LLC v. Centurytel Broadband Servs. LLC*, 778 F.3d 1327, 1331 (Fed. Cir. 2015) (listing elements of collateral estoppel, all of which are met here);

California court's thorough opinion provides a roadmap for rejecting them. *See Celltrion, Inc. v. Genentech, Inc.*, No. 18-CV-00274-JSW, 2018 WL 2448254, at \*5-8 (N.D. Cal. May 9, 2018).

*Second*, as explained in Genentech's opening brief (D.I. 41 at 13-14), Celltrion's recent actions cannot resurrect the patent dance that it abandoned in January. Celltrion makes no serious attempt to dispute this; instead, it wholeheartedly embraces a reading of the BPCIA that would allow a biosimilar applicant to ***unilaterally and indefinitely delay, then resurrect*** the patent dance. Celltrion agrees that "[§ 262(l)(4)(B)] gives the parties 15 days to negotiate and agree on a list of patents that will be the subject of a first round of litigation," but it contends that "nothing in [§ 262(l)(5)] suggests the biosimilar applicant must provide its (5)(A) designation on the very first day after the time to negotiate has expired." Opp. at 14. In other words, Celltrion argues that, if the parties fail to reach agreement within § 262(l)(4)(B)'s 15-day period, then the biosimilar applicant may indefinitely suspend the patent dance and unilaterally resume it at the applicant's convenience. The more logical reading of the statute—and certainly the one that is more consistent with the BPCIA's aim of a "streamlined patent resolution process . . . [that] will help ensure that litigation surrounding relevant patents will be resolved expeditiously," *Amgen*, 827 F.3d at 1063 (quoting BPCIA's legislative history)—is that the biosimilar applicant must comply with its obligations under § 262(l)(5)(A) immediately upon expiration of the 15-day period in § 262(l)(4)(B). There is nothing streamlined or expeditious about a process that lets one party unilaterally and indefinitely delay it.

Celltrion does, however, get one thing right: "section 262(l)(9)(B) is triggered by five specific (and specifically enumerated) failures to act," Opp. at 15, one of which is enumerated in

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*Galderma Labs. Inc. v. Amneal Pharm., LLC*, 921 F. Supp. 2d 278, 281 (D. Del. 2012) ("The pendency of an appeal does not diminish either the finality or binding effect of a trial court's holding.") (citing *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1382 (Fed. Cir. 1999)).

§ 262(l)(6)(C)(i). *See* 42 U.S.C. § 262(l)(9)(B). That provision requires a biosimilar applicant to “provide the Secretary [of Health and Human Services] with notice and a copy of” the reference product sponsor’s suit under § 262(l)(6)—in other words, the first-phase complaint that happens in a properly completed patent dance—“[n]ot later than 30 days after [the] complaint is served.” 42 U.S.C. § 262(l)(6)(C)(i). Celltrion does not even attempt to allege that it has done this, nor can it. Celltrion ended the patent dance in January, so no complaint under § 262(l)(6) was ever filed. And even if Celltrion’s attempts to revive the patent dance were deemed valid and Genentech’s protective suit<sup>8</sup> were deemed a complaint under § 262(l)(6)—two conclusions that would be inimical to the BPCIA’s structure and goals—Celltrion’s counterclaims would still be barred. Celltrion brought its counterclaims on July 3 (D.I. 36), but Genentech did not file its protective suit until July 11 (D.I. 1 in C.A. 18-1025). Celltrion could not possibly have complied with § 262(l)(6)(C)(i) before bringing its counterclaims.<sup>9</sup> This failure provides an independent basis to dismiss Celltrion’s counterclaims.

### III. CONCLUSION

Because Celltrion failed to complete the patent dance, its counterclaims are barred by § 262(l)(9)(B). Celltrion’s counterclaims should therefore be dismissed in their entirety.

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<sup>8</sup> Celltrion contends that Genentech’s protective suit is “specifically predicated on the understanding that Celltrion *did* complete the patent dance.” Opp. at 2-3. Not so. Genentech’s complaint in that case explains that Celltrion’s purported attempts to complete the patent dance were untimely but that the action was being filed out of an abundance of caution. D.I. 1, ¶ 14, C.A. No. 18-1025-GMS (D. Del.). And Genentech’s contemporaneous letter to the Court, D.I. 39, explains that this caution was necessary because Celltrion has engaged in gamesmanship related to the BPCIA’s limitation of remedies in other cases.

<sup>9</sup> Celltrion may try to create another loophole by arguing that it did not fail to act under § 262(l)(6)(C)(i) because the triggering event never occurred. But the need to layer loophole on top of loophole simply illustrates how untenable Celltrion’s position is. The more natural—and correct—interpretation of § 262(l)(9)(B) is that it requires the biosimilar applicant to complete the patent dance if it wishes to preserve its ability to bring declaratory-judgment claims.

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 7, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 7, 2018, upon the following at the email addresses indicated below:

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